

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**STATUS OF THE RURAL HEALTH
CLINIC PROGRAM**



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E X E C U T I V E S U M M A R Y

OBJECTIVE

To follow up on previous Office of Inspector General (OIG) recommendations concerning the appropriate location of Rural Health Clinics (RHC).

BACKGROUND

In 1996, OIG and the Government Accountability Office (GAO) issued reports that raised concerns about the inappropriate growth and location of RHCs. Both offices recommended changes that would ensure that RHCs are located in areas that would otherwise be underserved. Because of these reports, Congress, as part of the Balanced Budget Act of 1997 (BBA), amended section 1861(aa)(2) the Social Security Act to remove the permanent designation of RHCs and require timely review of shortage-designation areas. However, to date, the Centers for Medicare & Medicaid Services (CMS) has no regulations implementing the BBA's required changes.

To be eligible for RHC status, a clinic must be located in a "rural" and "underserved" area. The Rural Health Clinic Services Act of 1977 (the Act) defines "rural" as an area that the Bureau of the Census (Census) categorizes as a nonurbanized area. An "underserved" area is one that the Health Resources and Services Administration (HRSA) designated as medically underserved or experiencing a physician shortage. For shortage areas to be eligible under the RHC Program, the BBA required that HRSA review and update these areas every 3 years.

Under Medicare and Medicaid, RHCs receive cost-based reimbursement or a capped amount that is normally higher than a typical physician office visit. Payments for RHC services continue to increase and exceeded \$630 million in calendar year 2002.

FINDINGS

Two hundred seventy-nine RHCs are located in areas that HRSA has not designated as shortage areas or that Census has designated as urbanized areas. Sixty-one percent (169) of these RHCs are located in areas that HRSA has not designated as shortage areas. The remaining 39 percent (110) are located in urbanized areas defined by Census. Under the BBA, these RHCs would no longer maintain their designations as RHCs unless they receive exceptions as essential providers. CMS issued final regulations for the exception process.

However, because of a conflict with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS withdrew the regulations. In the absence of regulations, it is unclear how many of these 279 RHCs would meet the essential provider exception.

Another 946 RHCs are located in shortage-designated areas that HRSA has not reviewed or updated within a 3-year period. The BBA requires RHCs to be located in shortage areas that HRSA has designated or updated within the last 3 years. However, HRSA has not updated the shortage area designations for 26 percent of Health Professional Shortage Areas and 94 percent of the Medically Underserved Areas (MUA) where RHCs are located. As a result, 28 percent (946) of all RHCs are located in areas that do not meet the 3-year HRSA review requirement.

Rural and shortage criteria do not effectively identify areas that are truly rural and medically underserved. Although most RHCs are located in areas that meet the RHC Act's definition of rural, approximately 39 percent of RHCs are located in areas that Census considers urban because Census uses a broader definition of urban areas that includes urban clusters. HRSA's health care shortage-designation methods do not adequately measure medical underservice in that they exclude certain primary care practitioners and rely on an Index of Medical Underservice that GAO identified as being unreliable.

Current criteria result in RHC participation in areas with already existing health care delivery systems. RHCs are not required to demonstrate how they will improve access for Medicare and Medicaid beneficiaries. Consequently, RHCs can establish themselves near existing medical infrastructure with ease. For example, 90 percent of RHCs had three or more primary care provider sites within 25 miles of their locations. Two hundred sixteen RHCs (6 percent) are located in counties in metropolitan areas with populations over 1 million.

RECOMMENDATIONS

Over 7 years have passed since the enactment of the BBA and many of the problems identified in the previous OIG and GAO reports continue to exist. Attempts by CMS and HRSA to issue regulations to address the problems identified by these reports have not been successful. Because of the involvement by both HRSA and CMS with the RHC Program, OIG makes recommendations to both of these agencies.

Recommendations for HRSA

HRSA should review shortage designations within the requisite 3-year period. Because the RHC Program’s success in providing care to the rural underserved depends on the timeliness of HRSA’s designations, HRSA should review its designations made more than 3 years ago to assess the need for continued designation.

HRSA should publish regulations to revise its shortage-designation criteria. HRSA should issue regulations that would improve its shortage-designation criteria. These regulations should consider expanding the definition of a practitioner to appropriately account for the care that nurse practitioners and physician assistants provide. HRSA should also consider revising the MUA’s Index of Medical Underservice to include more precise measures of health status.

Recommendations for CMS

CMS should issue regulations to ensure that RHCs determined to be essential providers remain certified as RHCs. While we recognize that CMS did issue final regulations for the RHC Program and had to withdraw them, the lack of final regulations allows RHCs that no longer meet eligibility criteria to continue to receive cost-based reimbursement or a capped amount.

CMS should seek legislative authority or administratively require RHC applicants to document need and impact on access to health care in rural underserved areas. Because current law limits CMS’s ability to define rural and shortage areas, CMS could better ensure access to care for Medicare and Medicaid beneficiaries by imposing access requirements in addition to location requirements. In its comments to GAO’s 1996 report, the Department of Health and Human Services agreed that the shortcomings of the RHC certification process would be best addressed by reviewing other factors, such as need and community impact, in addition to the shortage designation and rural location.

AGENCY COMMENTS

HRSA concurred with our recommendations that it should review underserved designations that it has not updated in the last 3 years and that HRSA should publish regulations to revise its shortage designation criteria. HRSA also provided technical comments for which we made revisions where appropriate.

E X E C U T I V E S U M M A R Y

CMS concurred with the recommendation that it issue regulations to ensure that RHCs determined to be essential remain certified as RHCs. CMS is further considering our recommendation that CMS should seek legislative authority to require RHCs applicants to document need and impact on access to care as a requirement to receiving certification as an RHC.

OFFICE OF INSPECTOR GENERAL RESPONSE

We appreciate both HRSA's and CMS's response to our report. It is important that HRSA is implementing an automated application and review process that will reduce the review time for determining whether areas meet the underserved criteria. It is also important that CMS is committed to reissuing proposed and final regulations that would allow it to terminate those clinics that do not meet the basic location requirements unless they demonstrate that the clinics are essential community providers for their service areas.

We continue to believe that requiring current and prospective RHCs to provide additional evidence of community need would further the goal of assuring that RHCs are directed and maintained in rural communities with critical shortages of primary care providers. The establishment of further criteria would help limit the creation of new RHCs in areas with a concentration of viable providers but, more importantly, it would encourage the establishment of RHCs in areas with unmet need.

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OBJECTIVE

To follow up on previous Office of Inspector General (OIG) recommendations concerning the appropriate location of Rural Health Clinics (RHC).

BACKGROUND

In 1996, OIG issued a report that concluded that RHCs might not be located in appropriate locations. Based on these findings, OIG recommended that RHCs be located in shortage areas with accurate and up-to-date designations and that RHCs no longer meeting these criteria should lose their certification. Finally, OIG recommended that in addition to meeting the rural underserved designations, the Centers for Medicare & Medicaid Services (CMS) should require RHCs to document health care needs and anticipate how their establishment will impact this need in their community. Because of this report and a report issued by the Government Accountability Office (GAO), Congress required, as part of the Balanced Budget Act of 1997 (BBA), several changes to improve the RHC Program, which is codified at section 1861(aa) of the Social Security Act. This inspection reviews the RHC Program since passage of this law.

The Rural Health Clinic Program

The Rural Health Clinic Services Act of 1977 (RHC Act), Public Law 95-210, authorized the RHC Program in 1977. According to House Report No. 95-548(I), the purpose of the RHC Program was to address the problem of an inadequate supply of physicians serving Medicare and Medicaid beneficiaries in rural areas. At the time, many rural communities were unable to attract or sustain primary care physicians, and had come to rely on mid-level practitioners, such as physician's assistants and nurse practitioners for primary care services. However, Medicare and Medicaid did not generally reimburse the services delivered by these nonphysician practitioners. The RHC Act authorized Medicare and Medicaid reimbursement for services provided by nonphysician primary care practitioners in RHCs.

For operating in rural underserved areas, the RHC Act provides clinics certified as RHCs a payment rate for the care of Medicare beneficiaries equal to the lower of their reported costs or a predetermined capped amount. The capped amount in 2003 was \$66.72 per encounter, compared to \$51.13 for a typical office visit to a physician.

CMS is responsible for overseeing the RHC Program. To be eligible, applicants must meet two criteria related to location. First, the clinic must be located in an area that meets the RHC Act's definition of rural. Second, the RHC Act requires that the clinic be located in a Health Resources and Services Administration (HRSA) designated shortage area.

As of May 2003, there were 3,340 RHCs located in 1,500 counties in 44 States. The number of RHCs in the States ranged from Texas with the most RHCs at 336, to Rhode Island with only 1 RHC. In calendar year 2002, Medicare spent approximately \$312 million and Medicaid spent approximately \$321 million on RHC services.¹

Definition of Rural

Under the RHC Act, clinics applying for the RHC Program must not be located in an urbanized area as defined by the Bureau of the Census (Census).² Census defines "urbanized areas" as those with a population of over 50,000; consequently, CMS considers all areas with populations under 50,000 as rural.

For the 2000 Census, Census established a new designation for mid-sized areas to better distinguish the nation's urban and rural areas. In March 2002, Census issued final regulations to expand its definition of "urban" to include all territory, population, and housing units located within an:

- urbanized area – areas with populations of 50,000 or more, or
- urban cluster – areas with populations of more than 2,500, but less than 49,999.

These new, broader definitions do not apply to the RHC Program because the language of the RHC Act specifies that clinics cannot be located in an "urbanized area" and makes no mention of "urban clusters."

Definition of a Shortage Area

The RHC Act also requires that clinics be located in a HRSA designated shortage area. HRSA is responsible for identifying areas with shortages of primary care physicians and health care services. HRSA designates shortage areas for the purpose of directing placement of providers or program funding for nearly 30 departmental programs focused on alleviating access problems in such locations.

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For the RHC Program, CMS relies on two of HRSA's methods to identify shortage areas. One designates Health Professional Shortage Areas (HPSA), and the other designates Medically Underserved Areas (MUA).

In applying the HPSA designation, HRSA identifies areas in which there is a shortage of medical professionals in relation to the population or which contains a population group that HRSA determines has such a shortage. HRSA developed the HPSA system in 1978 as a way to designate areas for placement of National Health Service Corps providers. Section 332 of the Public Health Service Act requires HRSA to review HPSA designations annually. HRSA implemented this requirement by requiring HPSAs to provide new data every 3 years. As a result, in any given year HRSA reviews new data for one-third of the HPSAs.

In 2002, Congress passed the Health Care Safety Net Amendments of 2002 (Public Law 107-251), which amended section 332 of the Public Health Service Act to provide an automatic HPSA designation for clinics meeting the "charges for services" requirements. To meet the "charges for services" requirements, a clinic must: (1) prepare a fee schedule with adjustments made on the basis of the patient's ability to pay, and (2) not deny health services to individuals because of inability to pay. For an RHC to obtain automatic HPSA designation, HRSA requires an RHC to submit a Certificate of Eligibility and reflect "charges for services" requirements in its Policies and Procedures Manual. An automatic HPSA designation is valid for 6 years and is renewable for additional 6-year periods.

The MUA method identifies areas not receiving adequate health services for a variety of reasons, including provider shortages. Developed in 1973, based on an amendment to the Public Health Service Act, HRSA uses the MUA designation primarily to identify areas eligible to participate in the Community Health Center program. HRSA calculates an Index of Medical Underservice using four factors. These four factors are: (1) primary care physician-to-population ratio, (2) infant mortality rate, (3) percentage of population below the poverty level, and (4) percentage of the population aged 65 and older.

In addition, HRSA may designate areas as underserved at the request of a State's Governor. The Governor can select these areas based on unusual local conditions.

States are responsible for submitting a list of MUAs and Governor-designated areas to HRSA for approval. HRSA is responsible for

surveying and updating HPSAs. Unlike HPSAs, MUAs and Governor-designated areas are not subject to statutory requirements for regular review and update.

In 1996, Congress passed the Health Centers Consolidation Act requiring HRSA to consolidate its HPSA and MUA definitions into one system known as “medically underserved population.” On September 1, 1998, HRSA published in the Federal Register a Notice of Proposed Rulemaking [62 Federal Register 46537-46555], proposing updates to the HPSA and MUA designations. This update would have required a 3-year review for all shortage area designations. However, according to HRSA, due to the volume of comments received expressing concerns that the proposed new methods would eliminate many providers currently participating in departmental programs, it withdrew the proposed regulations.

As of June 2005, HRSA has yet to issue final regulations on the shortage-designation process. HRSA has not issued any further guidance regarding shortage designations.

Previous Assessments of the RHC Program

In July 1996, OIG issued a report entitled “Rural Health Clinics: Growth, Access, and Payment” (OEI-05-94-00040). The report concluded that RHCs might not be located in true shortage areas because some designations were outdated or inappropriate. Additionally, the report recognized that, as intended by the law, RHCs might provide increased access to care in some areas. However, there were no reliable data to measure the effect of RHCs on access to care.

Based on these findings, OIG recommended that CMS, along with HRSA, modify the certification process to increase State involvement and ensure the strategic placement of RHCs. OIG also recommended that RHCs be located in shortage areas with accurate and up-to-date designations and that those no longer meeting the criteria lose their certification. Finally, OIG recommended that in addition to meeting the rural underserved designations, CMS should require RHCs to document the need for health care services and anticipate how their establishment will impact the communities’ need.

CMS and HRSA agreed with most of OIG’s recommendations. CMS indicated that it would rely on HRSA to publish new regulations to revise the current shortage area designation system. HRSA accepted this responsibility and stated that, in addition, it would collaborate with

CMS in determining how to increase State involvement in the certification process.

In November 1996, GAO issued a report that echoed many of the OIG's findings and recommendations. "Rural Health Clinics: Rising Program Expenditures Not Focused on Improving Care in Isolated Areas" (HEHS-97-24) stated that the RHC Program had grown rapidly, but not in locations where Medicare and Medicaid populations were having difficulty obtaining primary care. GAO found the growth was concentrated in areas with established health care systems and RHCs were not decreasing the distance patients traveled to obtain health care. GAO concluded that broad eligibility criteria allowed RHCs to proliferate in areas where the need was minimal.

As did OIG, GAO recommended a legislative change that would restrict RHC certification to clinics in areas either with no other Medicare or Medicaid providers or to clinics demonstrating that existing providers will not accept new Medicare or Medicaid patients and that the clinics will expand access to these patients. In response, the Secretary of the Department of Health and Human Services (HHS) stated that current RHC Program eligibility criteria for defining rural and underserved areas do not go far enough to ensure that the program is directed and maintained in rural communities with critical shortages of primary care providers. The Secretary requested that HRSA improve its designation process for HPSAs and MUAs and require clinics applying for RHC certification to provide documentation of the need for health care services in the target community.

Improvements to the RHC Program: The Balanced Budget Act of 1997

Based on OIG and GAO work on the RHC Program, Congress amended the provision of the RHC Act that allowed RHCs to remain permanently designated (known as the "grandfather" provision) even if they no longer met the rural and shortage area criteria. This change required CMS to establish criteria to determine if those RHCs no longer meeting location requirements continue to be essential to the delivery of primary health care. The BBA also required that RHCs be located in areas that HRSA has reviewed within the previous 3-year period.

In December 2003, CMS issued regulations implementing the changes required by the BBA in its final regulations for RHC certification [68 Federal Register 74791-74818 (12/24/2003)]. CMS withdrew the final regulations based on a provision in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Public Law

108-173), which required that regulations take no longer than 3 years from the time an agency proposes them until they are final. CMS is planning to issue a new Notice of Proposed Rulemaking requesting public comments on regulations implementing the changes required by the BBA.

METHODOLOGY

Data Collection

For our data collection, we pulled information on all certified RHCs active as of May 2003 using CMS's Online Survey Certification and Reporting (OSCAR) system. To determine an RHC location, we obtained address information from OSCAR for all active RHCs. We also obtained address information for general short term hospitals, including Critical Access Hospitals (CAH) and Federally Qualified Health Centers (FQHC). FQHCs are clinics receiving grants under the Public Health Service Act or meeting the requirements for receiving a grant. We also reviewed Medicare's Participating Physician Directory for selected counties.

From Census, we obtained files from the Topologically Integrated Geographic Encoding and Referencing system for each of the counties in which an RHC was located. Using the Geographic Information System of SAS®, we geographically encoded the physical location of RHCs, general short term hospitals (including CAHs), and FQHCs. This encoding process determines the latitude and longitude of the location based on the street address, city, State, and zip code.

Analysis

To determine if RHCs meet the rural location requirement, we created county maps from the Topologically Integrated Geographic Encoding and Referencing files that displayed the urbanized areas. We also plotted urban clusters for 1,500 counties in which RHCs are located. Using the geographically encoded information, we plotted the location of RHCs, general short term hospitals (including CAHs), and FQHCs relative to urbanized areas and urban clusters in a county.

To determine whether RHCs are located within shortage-designation areas, we accessed HRSA's Geospatial Data Warehouse, which captures the designation of underserved areas. Using this data warehouse, we were able to determine whether a clinic was located in a HPSA, MUA, Governor-designated area, or a combination of the three. Also using HRSA data, we were able to determine the most recent certification of

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the shortage area for HPSAs, MUAs, and Governor-designated areas. We also obtained the current list of RHCs that have received automatic HPSA designation based on the Health Care Safety Net Amendments of 2002.

To compare the location of RHCs in relation to other primary care providers in a service area, we plotted the addresses of our selected primary care provider types within a 25-mile radius. We selected 25 miles because it is one of the tests HRSA applies to determine a service area. This mileage translates into approximately 30 minutes of travel time accessing interstates and primary roads. Although HRSA also calculates 30 minutes travel time using other road conditions³, we selected the 25-mile test as a reasonable proxy for a service area.

To understand the complexities of the RHC Program's location criteria, we reviewed all relevant laws and regulations. We also interviewed staff in CMS central office, selected CMS regional and State officials, and HRSA officials about the RHC Program.

Scope

This inspection only reviewed RHC Program eligibility criteria related to the location of clinics. We did not review other criteria RHCs must meet to receive RHC status.

In our analysis of the number of primary health care sites within a 25-mile service area, we only included short term hospitals (including CAHs), FQHCs, and RHCs to provide a conservative estimate of the types of primary care facilities available in the area. Our estimates are conservative in that we did not analyze the number of primary care practitioners (i.e., doctors, nurse practitioners, or physician assistants) at each of the provider sites in an area.

We did not attempt to measure the adequacy of service in an area or to evaluate how an area's service compared to HRSA's shortage-designation criteria. Finally, we did not attempt to determine whether RHCs had an impact on access to health care in rural underserved areas, as it was beyond the scope of our study.

Our review was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency.

Two hundred seventy-nine RHCs are located in areas HRSA has not designated as shortage areas or Census has designated as urbanized areas

Sixty-one percent (169) of these RHCs are located in areas that HRSA has not designated as shortage areas. The remaining 39 percent (110) are located in urbanized areas defined by Census.

While some of these RHCs will meet the eligibility criteria once HRSA reviews and continues the area's shortage designation, other RHCs will have to seek an exception for continued certification as an essential provider. CMS published regulations that would have allowed RHCs that no longer meet the eligibility criteria to apply for exceptions as essential providers. However, CMS withdrew these regulations because of a conflict with the MMA.

Another 946 are located in shortage-designated areas that HRSA has not reviewed or updated within a 3-year period

Although the BBA requires that RHCs be located in shortage areas that are reviewed every 3 years, we found that 28 percent of RHCs are located in areas where status has

not been reviewed within this timeframe. Since HRSA's designations for some areas have not been reviewed within a 3-year period, it is unknown whether these areas still satisfy criteria for a qualifying shortage designation for the RHC Program.

HRSA has not reviewed 94 percent of the MUAs where RHCs are located within the previous 3-year period.

Ninety-four percent of MUAs with RHCs do not meet the 3-year update requirement set forth in the BBA. HRSA does not have a required schedule for updating MUAs.

HRSA has not reviewed 59 percent of all MUA designations with RHCs in over 25 years. The length of time since an area's original MUA designation raises questions about the area's continued need for such a designation.

HRSA has not reviewed 26 percent of HPSA designations where RHCs are located within the required 3-year period.

Since January 2001, HRSA has not established or reviewed 26 percent of the HPSAs wherein RHCs are located. HRSA fails to meet the BBA's requirement for HPSA updates and does not comply with its own HPSA-specific requirement for 3-year updates. HRSA requires each HPSA to

submit an updated application every 3 years for review, yet 26 percent had not been reviewed during the required 3-year period.

Rural and shortage criteria do not effectively measure the areas that are truly rural and underserved

Problems with the RHC program were noted in the past and unsuccessful attempts were made by CMS and HRSA to correct them.

Our recent work in this area indicates that these problems still exist.

CMS is limited by the RHC Act’s definition of rural.

Although most RHC locations are appropriate given the RHC Act’s limited definition of rural, approximately 39 percent of RHCs are located in areas that Census considers urban using its expanded definition of urban areas. Only RHCs located in “urbanized areas,” as defined by Census, would not meet the statutory requirement to be certified as RHCs. All other RHCs, including RHCs located in areas defined by Census as “urban clusters,” meet the statutory criteria to be certified. Census uses the term “urbanized area” as only one component of its definition of urban. The Census’s complete definition of urban also includes “urban clusters,” which are areas with a population between 2,500 and 49,999.⁴

Applying other Federal criteria that measure urban influence reveals that RHCs are currently located in areas with significant urban influence. For example, in defining rural for the Medicare program, CMS has consistently used the definition of a Metropolitan Statistical Area as established by the Office of Management and Budget (OMB). Using OMB’s definition, 25 percent of current RHCs are located in metropolitan areas that would not qualify as rural under OMB’s criteria.

Using the Department of Agriculture’s Rural-Urban continuum codes, we found 834 RHCs located in metropolitan areas. Of these RHCs, 216 are located in counties in metropolitan areas with populations in excess of 1 million, 317 are located in counties in metropolitan areas with populations between 250,000 and 1 million, and 301 are located in counties in metropolitan areas with populations under 250,000. At the other end of the spectrum, we found only 413 RHCs, or 12 percent of all RHCs, located in completely rural counties not adjacent to a metropolitan county. These codes distinguish “metropolitan (metro) counties by the population size of their metro area, and nonmetropolitan (nonmetro) counties by degree of urbanization and adjacency to a metro

area or areas.”⁵ See Appendix A for a complete breakdown of RHCs categorized by Rural-Urban continuum codes.

CMS relies on HRSA’s health care shortage-designation systems which do not adequately measure underservice.

According to GAO, the accuracy of HRSA’s shortage-designation systems used for RHC certification is questionable for two reasons. First, HRSA’s systems do not consider all primary care resources when determining the need for additional practitioners. Second, the MUA’s Index of Medical Underservice does not yield current and effective information on an area’s supply of health care services.

HRSA has yet to revise the shortage-designation systems, despite the fact that both the Health Centers Consolidation Act of 1996 and the BBA require such improvements. HRSA’s 1998 proposed regulations would have implemented the required changes, but HRSA withdrew those proposed regulations and has yet to release a new rule. As a result, the RHC Program is still relying on shortage-designation systems that do not accurately reflect the availability of health care professionals and medical services in an area.

The ratio HRSA uses to measure physician shortages overstates them.

Although the RHC Act expanded the definition of primary care provider to include nurse practitioners and physician’s assistants, the current MUA and HPSA systems’ ratio of practitioners-to-population excludes these mid-level practitioners from its calculations. Originally, HHS planned to include these practitioners as 0.5 equivalent of a full-time physician, but excluded them because the scope of practice varied so much by State. GAO’s 1995 report found that because HRSA’s methodology omits nurse practitioners and physician’s assistants, the measure might overstate the need for additional physicians in HPSAs by 50 percent or more. In 1998, HRSA proposed once again to include these health care professionals as 0.5 of a full-time physician in the ratio, but as noted above, withdrew the proposed rule.

HRSA’s Index of Medical Underservice has been shown to be an ineffective measure of the availability of medical services.

According to GAO’s 1995 report, HRSA’s Index of Medical Underservice used to designate MUAs is ineffective for two reasons. First, the methodology HRSA used to develop the index is not based on “a clearly defined concept of medical underservice.”⁶ Second, HRSA’s system for designating an MUA compares an area’s current conditions to a median score on an index of medical underservice set in 1975. The threshold score for the MUA

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status has remained the same, except for minor changes made in 1981 when HRSA adjusted the weights for the infant mortality rate and population-to-physician ratio.

MUAs based on a score that uses standards from 1975 may not accurately reflect the availability of medical services in an area. For example, an analysis done by GAO found that less than half of the counties designated by HRSA as MUAs would qualify as MUAs using 1990 data.

Current eligibility criteria result in RHC participation in areas with already existing health care delivery systems

CMS's current eligibility criteria do not require new RHCs applicants to demonstrate how they

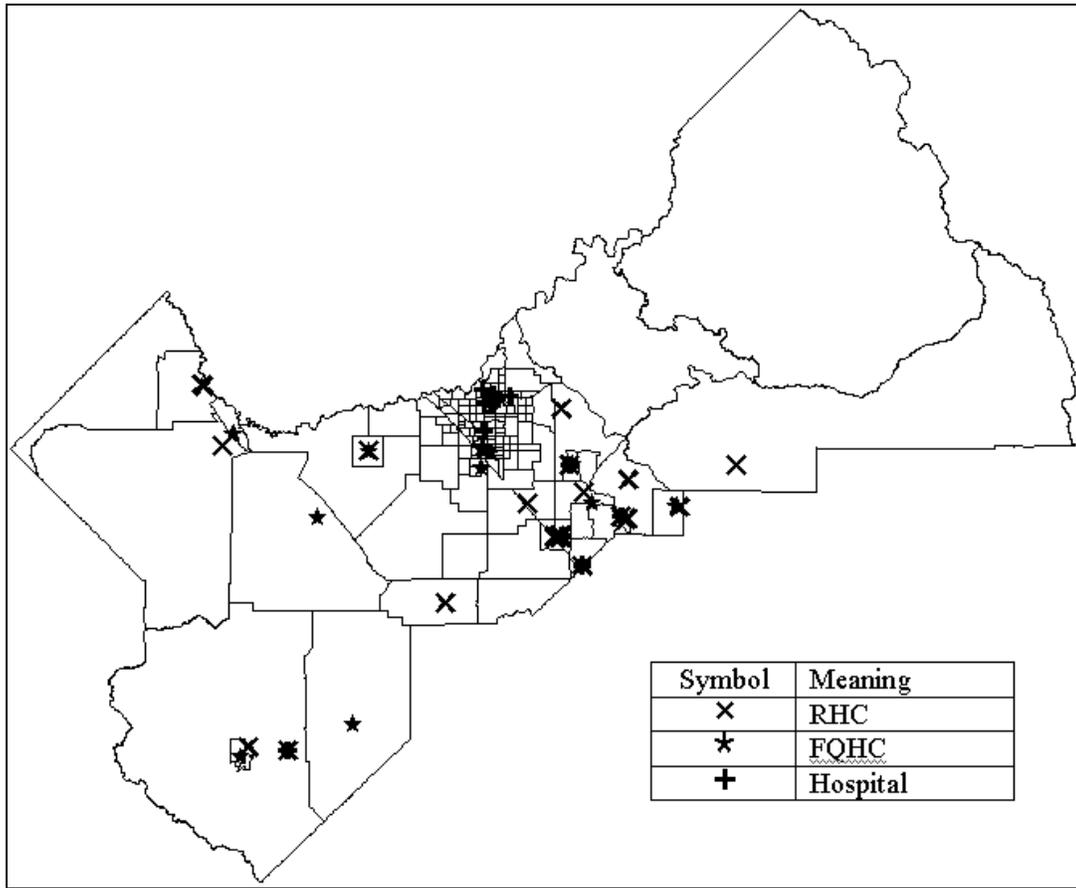
will improve access for Medicare and Medicaid beneficiaries.

Consequently, RHCs can easily establish themselves near existing medical infrastructure. For example, 90 percent of RHCs had three or more primary care provider sites within 25 miles of their locations. Ten percent of RHCs had 21 or more primary care sites located within 25 miles. These primary care sites include general short term hospitals (including CAHs), FQHCs, or other RHCs. We found that only 3 percent of RHCs have no other primary care within 25 miles of their locations. The following figure demonstrates an example of the concentration of RHCs and other primary care providers.

Figure 1, representing an actual county, demonstrates an example of the concentration of short term hospitals (including CAHs), FQHCs, and RHCs. In this example, there are 13 short term hospitals, 26 RHCs, and 12 FQHCs located in the county, which has an area of approximately 6,000 square miles. All RHCs are located within 25 miles of five or more primary care sites.

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Figure 1
Example of concentration of RHCs, FQHCs,
and hospitals



Source: Office of Inspector General analysis of OSCAR and Census data, 2005

Another example is a county that has a total population of approximately 62,000, with 7 primary cities ranging in population from 700 to 8,000. Approximately 10,000 of the total county's population are Medicare eligible and there are approximately 6,000 Medicaid beneficiaries. The county has seen a 15.5 percent increase in population from 1990 to 2000. HRSA designated the county as a HPSA that was last updated in September 2001.

Using OSCAR data, we identified 13 RHCs located across the approximate 700 square miles of the county. These clinics are in addition to 110 primary care physicians with 1 or more locations within the county and 4 general short-term hospitals. The average distance between each RHC in the county is 15.5 miles considerably less distance than the traditional 25-mile or 30-minute travel time test HRSA

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employs to determine appropriate service areas. All 13 RHCs have at least 3 other RHCs located within 15 miles of their locations.



R E C O M M E N D A T I O N S

The RHC Program's criteria related to location are not specific enough to ensure that the program's outcomes coincide with its goal to provide increased access to care for those Medicare and Medicaid beneficiaries living in rural communities with a shortage of primary care providers. Congress specifically created the RHC Program to benefit areas where population densities were insufficient to attract and retain physicians. Yet, it appears the current rural and shortage definitions may not direct placement of RHCs to areas of greatest need or prevent the addition of RHCs in areas with sufficient care.

Our analysis, as well as the 1996 OIG and GAO evaluations of the RHC Program, demonstrates that the RHC Program's basic eligibility requirements related to location may not address issues of Medicare and Medicaid beneficiaries' underservice in the way Congress intended. As it stands, CMS provides no quantifiable assurance that the Federal and State dollars spent each year on the RHC Program improve access to care in underserved areas.

The efforts of Congress, CMS, and HRSA to improve the RHC eligibility criteria have been unsuccessful. There are still issues related to the effectiveness of the shortage and rural location criteria resulting in RHCs participation in some service areas with extensive networks of health care providers.

Recommendations for HRSA

HRSA should review the underserved designations for the areas that have not been updated in the last 3 years.

The RHC Program's success in providing care to the rural underserved depends on HRSA's actions to review and update its shortage designations. Specifically, we recommend that HRSA review the areas with shortage designations more than 3 years old to assess the areas' designations.

HRSA's proposed rules of 1998 would have required a 3-year review of all shortage designations to ensure that programs using these designations receive accurate, updated information to make funding decisions. Due to the importance of these designations to the RHC program as well as to other departmental programs, HRSA should give priority to the review of shortage areas older than 3 years.

HRSA should publish regulations to revise its shortage-designation criteria.

To operate as effective eligibility criteria for the RHC Program, HRSA's shortage-designation methods need improvement. We recommend that HRSA revise the designation methods' criteria to improve the way it identifies shortage areas. In this revision, HRSA should develop new measures of health status and new methodologies for the designation systems. Additionally, HRSA should implement the requirement to review all designations every 3 years for all the programs that use the HPSA and MUA criteria.

Recommendations for CMS**CMS should issue regulations to ensure that RHCs determined to be essential providers remain certified as RHCs.**

Over 7 years have passed since the enactment of the BBA and many of the problems identified in the previous OIG and GAO reports continue to exist. While we recognize that CMS published final regulations for the RHC Program and had to withdraw them, the lack of regulations may be allowing RHCs that no longer meet eligibility criteria to continue to receive cost-based reimbursement.

CMS should seek legislative authority or administratively require RHC applicants to document need and impact on access to health care in rural underserved areas.

We believe the apparent ease with which the RHCs meet current location criteria has created payment incentives to locate RHCs in service areas that already have extensive health care delivery systems for Medicare and Medicaid beneficiaries. Because current law limits CMS's ability to define rural and shortage areas, CMS could better ensure access to care for Medicare and Medicaid beneficiaries by requiring clinics to meet other RHC eligibility factors in addition to the location requirements.

This recommendation is consistent with prior OIG and GAO recommendations. In its comments to GAO's 1996 report, HHS agreed that the shortcomings of the RHC certification process would be best addressed by reviewing other factors, such as need and community impact, in addition to the shortage designation and rural location. Despite this statement, CMS has not added additional eligibility criteria for RHC certification. CMS has not developed any performance measures related to RHC Program goals, making it difficult to assess what impact, if any, RHCs have on improving beneficiaries' access to care.

R E C O M M E N D A T I O N S

The final regulations that CMS withdrew indicated that the agency intended to implement our recommendation for some existing RHCs, but not for new applicants. Section 4205(d) of the BBA requires CMS to terminate RHC status for clinics no longer located in rural or underserved areas, except for those RHCs that are determined to be essential to the delivery of primary care. Under the regulations that CMS withdrew, clinics receiving essential provider status would have had to meet certain conditions designed to demonstrate how the clinic's presence affects the health care of the community. For example, an RHC would have had to show that it is the only participating primary care provider actively accepting and treating Medicare, Medicaid, and low-income beneficiaries within 30 minutes travel time, or that it treats a majority of these beneficiaries compared to other providers in close proximity, including other RHCs.

We believe that requiring current and prospective RHCs to provide additional evidence of community need would further the goal of assuring that RHCs are directed and maintained in rural communities with critical shortages of primary care providers. The establishment of further criteria would help limit the creation of new RHCs in areas with a concentration of viable providers, and more importantly, it would encourage the establishment of RHCs in areas with unmet need.

AGENCY COMMENTS

HRSA concurred with our recommendations that it should review underserved designations that it has not updated in the last 3 years and that HRSA should publish regulations to revise its shortage-designation criteria. HRSA also provided technical comments for which we made revisions where appropriate.

CMS concurred with the recommendation that they should issue regulations to ensure that RHCs determined to be essential remain certified as RHCs. CMS is further considering our recommendation that it should seek legislative authority to require RHCs applicants to document need and impact on access to care as a requirement for receiving certification as a RHC. See Appendix B for the full text of the agency comments.

OFFICE OF INSPECTOR GENERAL RESPONSE

We appreciate both HRSA's and CMS's response to our report. It is important that HRSA is implementing an automated application and

R E C O M M E N D A T I O N S

review process that will reduce the review time for determining whether areas meet the underservice criteria. It is also important that CMS is committed to reissuing proposed and final regulations that would allow it to terminate those clinics that do not meet the basic location requirements unless they demonstrate that the clinics are essential community providers for their service areas.

We continue to believe that requiring current and prospective RHCs to provide additional evidence of community need would further the goal of assuring that RHCs are directed and maintained in rural communities with critical shortages of primary care providers. The establishment of further criteria would help limit the creation of new RHCs in areas with a concentration of viable providers, and more importantly, it would encourage the establishment of RHCs in areas with unmet need.

▶ E N D N O T E S

¹ The reported Medicaid spending is underestimated because of incomplete data.

² Public Law 95-210.

³ HRSA standard uses 20 miles to approximate 30 minutes of travel under normal conditions on primary roads and 15 miles for travel on flat terrain or interstate highways.

⁴ An urban cluster consists of a contiguously settled core of census block groups and census blocks with populations between 2,500 and 49,999.

⁵ <http://www.ers.usda.gov/briefing/rurality/RuralUrbCon>.

⁶ “Health Care Shortage Areas: Designations Not a Useful Tool for Directing Resources to the Underserved” (GAO/HEHS-95-200, September 1995), p. 50.

RHCs by Rural-Urban Continuum Codes	
2003 Rural-Urban Continuum Codes	Rural Health Clinics
County in metro area with 1 million population or more	216
County in metro area of 250,000 to 1 million population	317
County in metro area of fewer than 250,000 population	301
Nonmetro county with urban population of 20,000 or more, adjacent to a metro area	281
Nonmetro county with urban population of 20,000 or more, not adjacent to a metro area	153
Nonmetro county with urban population of 2,500-19,999, adjacent to a metro area	823
Nonmetro county with urban population of 2,500-19,999, not adjacent to a metro area	588
Nonmetro county completely rural or less than 2,500 urban population, adjacent to metro area	248
Nonmetro county completely rural or less than 2,500 urban population, not adjacent to metro area	413
Overall Total	3,340

Source: Online Survey Certification and Reporting and Department of Agriculture Rural-Urban Continuum Codes, 2004



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

MAY 18 2005

DATE:

TO: Daniel R. Levinson
Acting Inspector General

FROM: Mark B. McClellan, M.D., Ph.D. *MM*

SUBJECT: Office of Inspector General's Draft Report: "Status of the Rural Health Clinic Program" (OEI-05-03-00170)

Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report that was prepared as a follow up to a previous OIG report and Government Accountability Office (GAO) work on the Rural Health Clinic (RHC) Program that identified inappropriate growth and location of RHCs. The subject report raises concerns regarding the certification and participation of RHCs in areas with already existing health care delivery systems.

Although the majority of participating RHCs are serving very rural underserved areas, there are over two hundred clinics (out of 3500) that are no longer serving an area formally designated as rural and/or medically underserved. To be eligible for RHC cost-based reimbursement and coverage benefits, a clinic must be located in a "rural" and "underserved" area.

As indicated by the OIG, several years have passed since the enactment of the Balanced Budget Act of 1997 (BBA), and many of the problems identified in the previous OIG and GAO reports continue to exist. The original reports analyzed the significant growth of RHCs and the impact on the Medicare and Medicaid budgets. Both reports concluded that the number of RHCs is growing out of proportion to the need and some RHCs remain in the program after the need for payment incentives no longer exists. They also concluded that the payment methodology for provider-based RHCs lacks sufficient cost controls and recommended establishing payment limits and screens on reasonable costs for these providers.

The findings and recommendations from the original reports assisted the Centers for Medicare & Medicaid Services (CMS) in drafting and proposing statutory changes to the RHC Program, which were approved by Congress in the BBA. Although most of the RHC Program changes in the BBA have already been implemented, such as the imposition of payment caps and screens on provider-based RHCs, CMS agrees that the BBA provision that provides CMS with the authority

Page 2 – Daniel R. Levinson

to disqualify non-essential clinics from the RHC Program that no longer meet basic location requirements (rural and underserved) needs to be implemented as soon as possible.

The CMS appreciates that the OIG reviewed this issue to apprise CMS that some of the problems identified in the first RHC study still exist. For example, a significant number of clinics remain in the RHC Program despite the fact that they no longer meet basic location requirements for participation. CMS agrees that these clinics should not continue to receive cost-based reimbursement, which is normally higher than Medicare and Medicaid physician fee schedule payments, unless they can demonstrate that they are essential community providers for their service area.

OIG Recommendation

The CMS should issue regulations to ensure that RHCs determined to be essential remain certified as RHCs. The lack of final regulations allows RHCs that no longer meet eligibility requirements to continue to receive enhanced Medicare and Medicaid reimbursement.

CMS Response

Although the final RHC rule was issued on December 24, 2003, CMS suspended enforcement of the rule due to section 902(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which requires CMS to publish final regulations based on the previous publication of a proposed regulation within 3 years except under exceptional circumstances. CMS intends to reissue new proposed and final RHC rules early next year to comply with section 902 of the MMA. Consequently, until the new rule is finalized CMS cannot implement the process and criteria for terminating clinics from the RHC Program that no longer satisfy basic location requirements and granting exceptions from RHC disqualification to clinics deemed essential.

OIG Recommendation

The CMS should seek legislative authority or administratively require RHC applicants to document need and impact on access to health care in rural areas. CMS could better ensure access to care for Medicare and Medicaid beneficiaries by imposing access requirements in addition to current statutory location requirements (rural and underserved).

CMS Response

The CMS is further considering this recommendation. CMS may not have the statutory authority to impose such a condition of participation on RHCs. Also, it could be very difficult to create national standards to appropriately address the specific conditions and circumstances within every rural community.

We appreciate the efforts that the OIG has made on this issue. We agree that the BBA provision pertaining to the disqualification of non-compliant RHCs needs to be implemented as soon as possible. The full implementation of the BBA changes would allow the program to better target areas of greatest need and prevent new and/or continuation of RHCs in areas with sufficient medical care.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

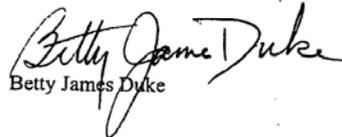
JUN 3 2005

Rockville, Maryland 20857

RECEIVED
2005 JUN 27 PM 3:34
OFFICE OF INSPECTOR
GENERAL

TO: Acting Inspector General
FROM: Administrator
SUBJECT: Office of Inspector General Draft Report, "Status of the Rural Health Clinic Program" (OEI-05-03-00170)

Attached please find the Health Resources and Services Administration's comments on the recommendations in the Office of Inspector General Draft Report, "Status of the Rural Health Clinic Program." HRSA previously provided general and technical comments on this report. Staff questions may be referred to Gail Lipton on (301) 443-6509.


Betty James Duke

Attachment

**Comments of the Health Resources and Services Administration on the
Recommendations of the Office of Inspector General Draft Report, "Status of the
Rural Health Clinic Program" (OEI-05-03-00170)**

The Health Resources and Services Administration (HRSA) appreciates the opportunity to provide comments on the recommendations in this Office of Inspector General (OIG) draft report.

OIG Recommendation

HRSA should review the underservice designations for the areas that have not been updated in the last three years.

HRSA Response

We concur with this recommendation. An automated application and review process is being implemented. Other changes being considered should also reduce the application and review time.

Currently, HPSA reviews are initiated after the full three year period is completed. The current level of resources, both at the State and Federal level, does not allow these reviews to be completed in a shorter timeframe. The actual submission of updates, review and action takes place during the fourth or possibly the fifth year depending on the number of requests and the complexity of these requests. When a Rural Health Clinic (RHC) Certification eligibility is pending, HRSA will give it a priority ahead of other cases that were submitted before it. In addition, HRSA staff have worked with RHCs to provide technical assistance and to make all parties aware of the pending deadlines for update.

OIG Recommendation

HRSA should publish regulations to revise its shortage-designation criteria.

HRSA Response

We concur with this recommendation. HRSA has submitted a draft "Notice of Proposed Rulemaking" which is in final review by the Department prior to submission to OMB.



A C K N O W L E D G M E N T S

This report was prepared under the direction of William C. Moran, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Ann Maxwell, Assistant Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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